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PATENT

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Applicant: R. Vasquez Lipi

Examiner: Yu, Gina C.

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For: TOPICAL MEDICAMENT FOR SKIN INJURIES AND DISORDERS

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents

Washington, DC 20231

Sir:

I, Dr. L. K. Tabuke *MBcHB, MPH*, do hereby make the following declaration:

1. I am currently on staff at Kenyatta National Hospital, Nairobi, Kenya.

2. The following experiments were carried out by me or under my direct supervision and control.

3. A COMPARATIVE STUDY OF EFFICACY BETWEEN SENCIL® OINTMENT AND OINTMENT B

Summary

We evaluated and compared the efficacy of Sencil ointment and Ointment B in the relief of minor skin lesions in 60 patients of whom 36 were female and 24 were male. The mean age of the patients was 28.5 years.

Sencil ointment contains cod liver and petrolatum as the active ingredient and a mixture of the following olive oil, almond oil, castor oil, sunflower oil, and beeswax. Ointment B contains olive oil and beeswax in approximately equal proportions.

4. ***Introduction***

The skin is the largest organ on the body, and is made up of several different components, including water, protein, lipids and different minerals and chemicals. On average the skin weighs about six pounds. The main function of the skin is protection from infections and germs. The skin regenerates approximately every twenty seven (27) days. Proper skin care is essential to maintaining the health and vitality of this protective organ.

Minor skin lesions are a common occurrence in any clinical set up. The lesions we evaluated included sunburn, dermatitis, insect bites, burns and abrasions. The aim of the present study was to compare the efficacy of these two ointments in the management of the above minor skin lesions.

5. ***Materials and Methods***

The study was carried out between February and March 2005 at the dermatology outpatient clinic of Kenyatta National Hospital, Nairobi, Kenya. The study consisted of 60 participants, 36 females and 24 males with various minor skin ailments. The participants were randomly assigned to either one of the two ointments. Prior to recruitment all patients gave an informed consent, for those below 18 years a legal guardian who happened to be the parents in all seven cases gave the consent. The patients were given appropriate instructions on how to apply the ointment. They were to apply the ointment twice a day after ensuring that the area was clean. The patient was examined and sent to the laboratory for basic blood works, which included a full blood count, and a urinalysis. Follow up and review was done on day 5, a follow up exam was done and the patient reported on what day the symptoms disappeared and the results were recorded. No further follow up was deemed necessary.

6. ***Results***

The primary outcome measure was resolution of the presenting symptom; this was assessed subjectively by asking the patient how they felt and objectively by examining the patient on day 5, after treatment. The patient would then report when the symptoms disappeared and this would be recorded on the patients' card. Analysis was done using Chi-square and F-test a form of ANOVA for computation of variance between two variables. The patients in the two treatment arms were similar in terms of age and sex, as seen from the p-value=0.000, and therefore comparability was justified. See table 1 below.

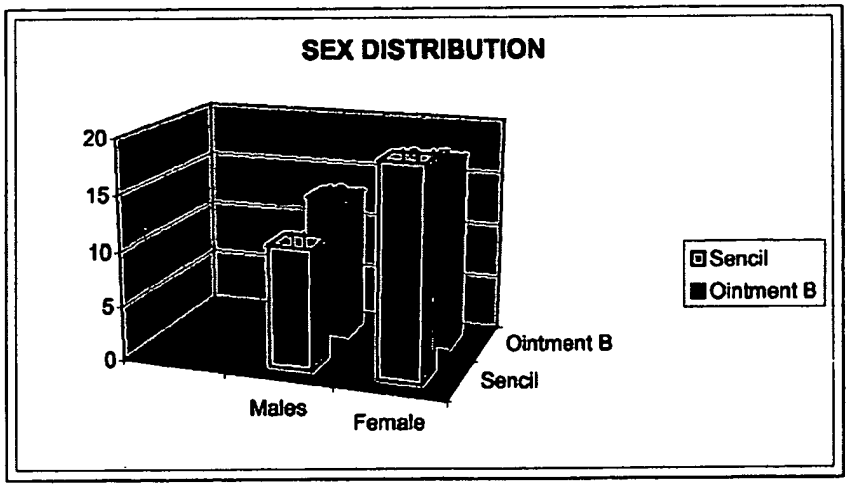
Table 1.

Age and sex distribution of 60 patients with skin lesions

Age range (yrs)	Male	Female	Total no of patients
>25	6	12	18
25-35	5	6	11
35-40	5	8	13
40-45	4	6	10
>45	4	4	8
Total	24	36	60

p-value=0.000 < 0.05. Statistically insignificant. The two treatment arms are similar.

Figure 1.



The results show that there is no difference between sex distribution in the two treatment arms p-value= 0.000. The two groups are comparable.

Table 2.

Presenting symptoms in order of frequency in 60 patients with skin lesions

Symptom	Sencil	Ointment B	Total
Itching	8	9	17
Dryness	10	8	18
Rash	7	7	14
Pain	5	6	11
Total	30	30	60

Table 3.

Skin Lesions seen in patients in KNH
Total number of cases = 60

Type of lesion	Sencil	Ointment B	Total
Dermatitis	7	9	16
Sunburn	7	5	12
Burn	5	5	10
Abrasion	6	7	13
Insect bite	5	4	9
Total	30	30	60

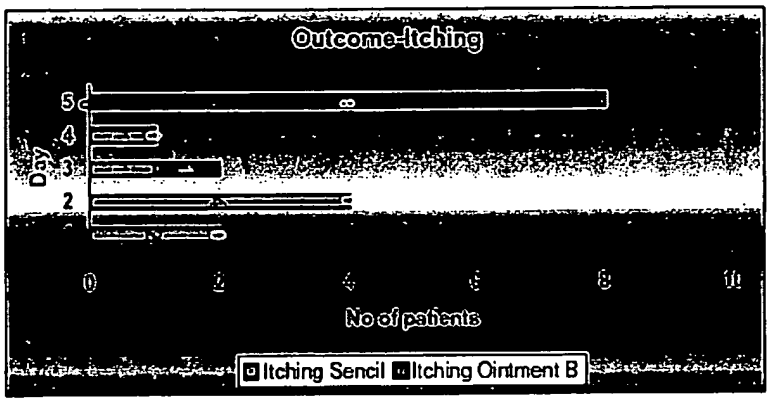
Table 4.

OUTCOME MEASURES-day symptoms cleared

		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	Total
Symptom							
Itching	Sencil	2	4	1	1	0	8
	Ointment B	0	0	1	0	8	9
Dryness	Sencil	3	5	2	0	0	10
	Ointment B	0	0	1	3	4	8
Rash	Sencil	1	2	3	1	0	7
	Ointment B	0	0	1	3	4	7
Pain	Sencil	1	3	1	0	0	5
	Ointment B	0	0	1	2	3	6
							60

Figure 2.

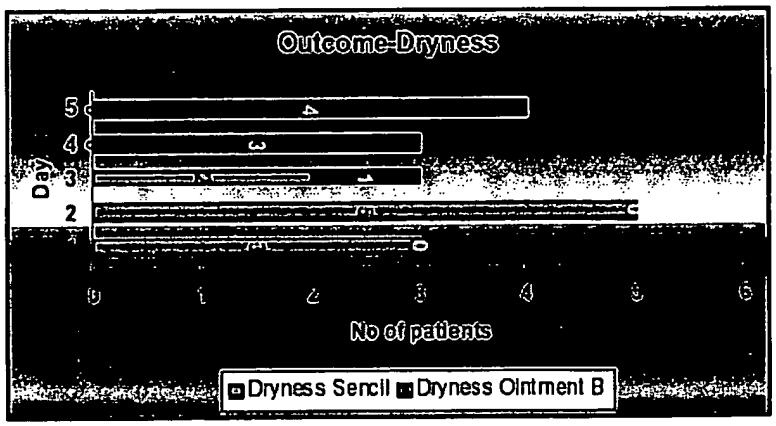
Resolution of itching



p-value= 0.0675 Statistically significant- there is a difference between the two treatments.

On the first day after starting treatment, two patients on Sencil reported relief in itching, while none on ointment B reported any relief.
On the second day after starting treatment four patients on Sencil reported relief in itching, while none on ointment B reported any relief.
On the third day after starting treatment, one patient on Sencil and one patient on ointment B reported relief in itching.
On the fourth day after starting treatment, one patient on Sencil reported relief in itching while none on ointment B reported any relief.
On the fifth day after starting treatment the remaining eight patients on Ointment B reported some relief in itching.

Figure 3.



Resolution of dryness

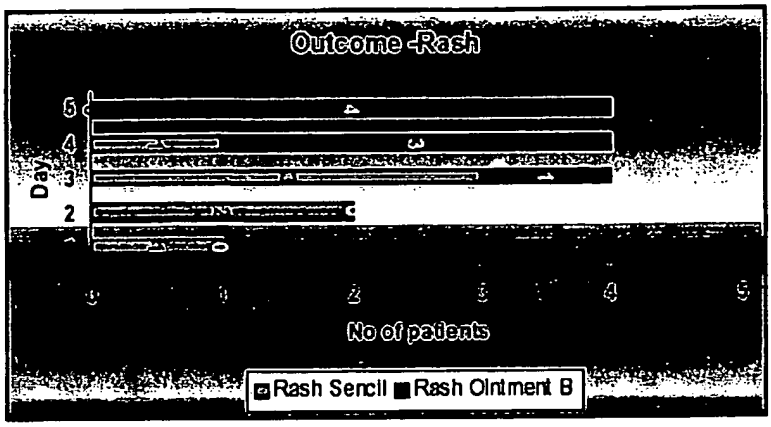
p-value= 0.0471 Statistically significant-there is a difference between treatments.

On the first day after starting treatment, three patients on Sencil reported relief in dryness, while none on ointment B reported any relief.

On the second day after starting treatment five patients on Sencil reported relief in dryness, while none on ointment B reported any relief.
On the third day after starting treatment, two patients on Sencil and one patient on ointment B reported relief in dryness.
By the third day all the patients on Sencil had experienced relief in their symptoms.
On the fourth day after starting treatment, three patients on ointment B reported relief in dryness.
On the fifth day after starting treatment the remaining four patients on Ointment B reported some relief in dryness.

Figure 4.

Resolution of rash

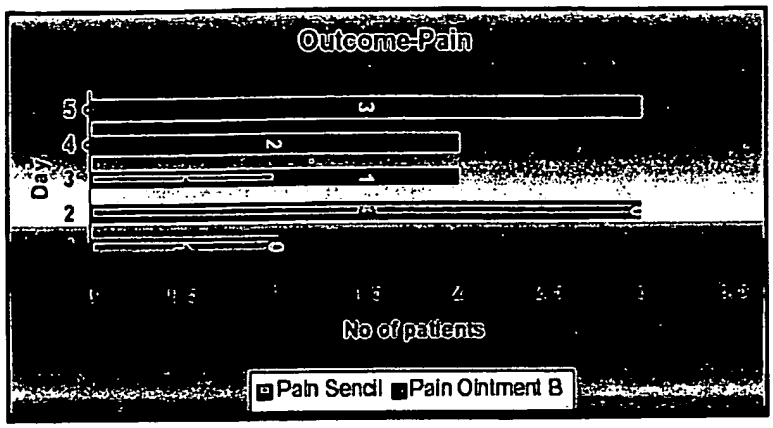


p-value = 0.0424 Statistically significant-there a difference between the treatments.

On the first day after starting treatment, one patient on Sencil reported resolution of the rash, while none on ointment B reported any relief.
On the second day after starting treatment two patients on Sencil reported resolution of rash, while none on ointment B reported any relief.
On the third day after starting treatment, three patients on Sencil and one patient on ointment B reported resolution of the rash.
On the fourth day after starting treatment, one patient on Sencil and three on ointment B reported resolution of the rash.
On the fifth day after starting treatment the remaining four patients on Ointment B reported some relief in the rash.

Figure 5.

Relief of pain



p-value = 0.4692 Statistically insignificant-there is **NO** difference between treatments.

On the first day after starting treatment, one patient on Sencil reported relief in pain, while none on ointment B reported any relief.
On the second day after starting treatment three patients on Sencil reported relief in pain, while none on ointment B reported any relief.
On the third day after starting treatment, one patient on Sencil and one patient on ointment B reported relief in pain
By the third day all the patients on Sencil reported relief.
On the fourth day after starting treatment two patients on ointment B reported relief in pain.
On the fifth day after starting treatment the remaining three patients on Ointment B reported relief in pain.

7. The purpose of this study was to compare and evaluate the effects of Sencil ointment and Ointment B. Based on the findings of this study, the results demonstrate that Sencil ointment was overall superior to Ointment B. The above results indicate that there was both a statistical and a clinical difference between the treatment arms for itching, dryness and rash. Sencil showed superior outcomes in all three cases. However, in the case of pain the two ointments were the same; none was superior to the other.

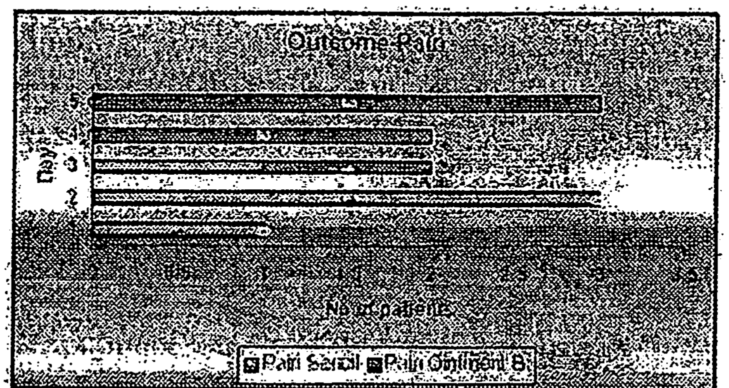
8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: _____ By: _____

Dr. L. K. Tabuke *MBcHB, MPH*

Figure 5:

Relief of pain



p-value = 0.4692 Statistically insignificant there is NO difference between treatments.

On the first day after starting treatment, one patient on Sencil reported relief in pain, while none on ointment B reported any relief.
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Dated: 29/09/05

By: [signature]
Dr. L. K. Tabuke *MBcHB, MPH*

RESUME

Name: Lydia Kathleen Tabuke.

Address: P.O. Box 55398, Nairobi. Kenya.

Phone: Mobile: 254-0722 513 602. Office: 254-20-224233

Email: tabuke@nimea-ea.org

Education:

- Masters in Business Administration- Strategic Management-MBA, University of Nairobi, Kenya -Expected graduation, September 2006.
- Masters in Public Health –International Health & Epidemiology, MPH 2002: Johns Hopkins University, Bloomberg School of Public Health, Baltimore, Maryland, USA.
- Bachelor of Medicine and Bachelor of Surgery MBChB 1992: University of Nairobi Medical School, Nairobi, Kenya.
- Kenya Advanced Certificate of Education KACE-Loreto High School, Limuru. 1986.

Experience:

NIMEA-Network for Information Monitoring and Evaluation of Antiretroviral Therapy in East Africa -(2005-to date)
Director
Co-founder of NIMEA. An NGO whose main objective is to develop an interactive, reliable repository of information on all aspects Anti retroviral Therapy-ART, to both the patients and caregivers.

Kenyatta National Hospital- (2003-to date)
Senior Medical Officer

- Attend medical out patient clinic- follow up of patients with chronic conditions, review medications and refill prescriptions.
- Diagnoses, Prescription of medications and therapies for treatment of diseases and disorders based on patient medical history and results of physical assessment.
- Participation and coordination of clinical trials in collaboration with other partners- University of Nairobi, Kenya Medical Research Institute (KEMRI).

Baltimore City (2002-2003)
Department of Public Health –Intern Project Coordinator- BCC Program

- Provide technical support to the Baltimore City department of public health in the planning, implementing and monitoring of programmes to scale up behavioral changes aspects related to HIV/STI among the inner city population.
- Supervision of 15 team members in implementing the strategies.

Dr. P.W. Kamau & Associates Clinic (2000-2001)
Medical Officer

- Perform physical examinations of new and existing patients at both the clinic and hospital-inpatients
- Diagnoses and treats disease and disorders based on patient medical history and results of physical assessment.
- Prescribes medications and therapies for treatment and preventive care.
- Instruct patients and their families regarding procedures performed, home care and follow up.
- Preventive health care and treatment of HIV patients, this included
  -Voluntary counseling and testing (VCT)
  -Prevention of maternal-to-child transmission (MTCT) of HIV, which includes provision of highly active antiretroviral therapy (HAART), MTCT Plus, and other related aspects of comprehensive care.

Kenyatta National Hospital (1995-2000)
Medical Officer

- Perform physical examinations of new and existing patients at both the clinic and hospital.
- Diagnoses and treats disease and disorders based on patient medical history and results of physical assessment.
- Prescribes medications and therapies for treatment and preventive care.
- Instruct patients and their families regarding procedures performed, home care and follow up.
- Preventive health care and treatment of HIV patients, this included
  -Voluntary counseling and testing (VCT)
  -Prevention of maternal-to-child transmission (MTCT) of HIV, which includes provision of highly active antiretroviral therapy (HAART), and other related aspects of comprehensive care.
- Perform other tasks as required.

Postdoctoral Training:

- Fellowship: International Fellow Pediatric Infectious Disease-Albany Medical Center, Albany NY USA 2001-2002.
- Internship: Armed Forces Memorial, Nairobi, Kenya. 1993-1994.

Professional Associations:

- Kenya Medical Women's Association (KMWA).
- American Public Health Association (APHA).
- Kenya Medical Association (KMA).

Licensure and Certification:

- Kenya Medical Board of Practitioners.
- ECFMG-USMLE Certificate (2000).

Publications:

- Female Gender vulnerability and HIV infection in Kenya- Dissertation MPH 2002, John Hopkins Bloomberg School of Public Health.
- Survey of condom use among hospital staff Nairobi Hospital and KNH- Tabuke L K and Professor G.N. Lule in progress.

Conferences attended:

- International HIV conference - Nairobi Kenya 2002, 2005
- Clinical Trials Unit Meeting- Johannesburg South Africa March-April 2005 NIAID Division of AIDS (DAIDS)

Special Skills:

- Proficient in computer applications.
- Strong communication, leadership and people management skills.
- Proficient in English, Luyhia and Kiswahili.
- Good knowledge of HIV/AIDS policy, planning and programming, particularly relating to care and public health.
- Clinical trials coordination and supervision.